C3

8. The soluble film preparation according to claim 1, in which the oligosaccharide is reducing maltose starch syrup.

C4

11. The soluble film preparation according to claim 1, in which the compound is nilvadipine, the additional edible polymer is hydroxypropyl cellulose, and the starch syrup is reducing maltose starch syrup.

REMARKS

Claim 12 has been cancelled. Claims 1, 4, 8, and 11 have been amended to further clarify the subject matter of the invention. No new matter has been added by virtue of the amendments because they are supported in the specification. Support for the claim amendments are found throughout the specification and the claims as filed, e.g., on page 9, line 11 through page 10, line 14, Example 15, Example 21, page 17, lines 3-11 ("Elution Test") and Figure 1.

Prior to the filing of this Continued Prosecution Application, the last substantive Office Action (Paper No. 8) issued in connection with the application set forth the rejections set out below. The amendment filed on October 18, 2002 in response to the Office Action was not entered. Rather than request entry of that amendment, the Applicants request entry of the within amendment.

Applicants respectfully request reconsideration of the application in light of the above amendments and the following discussion.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Claims 1-3, 5-8, 10 and 12 are rejected under 35 U.S.C. §102(b) as anticipated by Fuchs, *et al.* (U.S. Patent No. 4,136,145, "Fuchs").

Applicants respectfully traverse this rejection. The cited reference does not teach the presently claimed soluble film preparation.

As amended, the claims are to a soluble film preparation comprising a drug, edible polymer, and either a monosaccharide or an oligosaccharide, formed into a film by spreading and drying that has an elution rate of more than about 50% per 10 minutes and the drug is a compound that forms a solid solution with the polymer to enhance internal absorption. Solid solutions of exemplary drugs and polymers that enhance the absorption of the drugs are described in the specification on page 9, line 26 to page 10, line 14. Furthermore, the elution rate of more than about 50% per 10 minutes is rapid and improved.

While Fuchs may disclose a soluble film preparation for drug delivery, nowhere in Fuchs does the disclosure teach or suggest a single layer soluble film preparation that is obtained by spreading and drying, has an elution rate of more than about 50% per 10 minutes, and contains a drug and an edible polymer that forms a solid solution to enhance internal absorption of the drug.

Applicants respectfully request reconsideration and withdrawal of the rejection.

Thus, all the claims are allowable over this reference.

Claims 1-12 are rejected under 35 U.S.C. §103(a) as obvious over Fuchs, *et al.* in view of Oyangui, *et al.* ("Oyangui").

Applicants respectfully traverse this rejection. The cited references do not obviate the presently claimed soluble film preparation.

As claimed, the invention is a soluble film preparation comprising a drug, edible polymer, and either a monosaccharide or an oligosaccharide, formed into a film by spreading and drying that has an elution rate of more than about 50% per 10 minutes

and the drug is a compound that forms a solid solution with the polymer to enhance internal absorption.

Oyangui does not make up for the deficiencies of Fuchs. Oyangui appears to teach the anti-inflammatory effects of nilvadipine on ischemic and carrageenan paw edema in rats and mice. Indeed, the reference does not disclose any other composition with which nilvadipine may be administered. There is no suggestion in Oyangui to use the drug nilvadipine in the soluble film preparation of Fuchs to arrive at the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Thus, all the claims are allowable over these references.

Claim 12 is rejected under 35 U.S.C. §103(a) as obvious over Fuchs, *et al.*, and further in view of Terada, *et al.* (U.S. Patent No. 5,102,950, "Terada").

Applicants respectfully traverse this rejection. As amended, the claims are not obvious over the cited references.

The instant claims are directed to a soluble film preparation comprising a drug, edible polymer, and either a monosaccharide or an oligosaccharide, wherein the film is formed by spreading and drying and has an elution rate of more than about 50% per 10 minutes and wherein the drug is a compound that forms a solid solution with the edible polymer to enhance internal absorption. As shown in the Examples, the resulting thin film is obtained by spreading and drying which is a simple and economic production method that does not require a machine such as an extruder.

As discussed above, Fuchs may disclose a soluble film preparation for drug delivery but nowhere does the reference teach or suggest a soluble film preparation formed by spreading and drying and has an elution rate of more than about 50% per

10 minutes that contains both a drug and an edible polymer that forms a solid solution to enhance internal absorption of the drug.

Terada appears to disclose water soluble films containing a polymer that are used as packaging dry materials or liquids containing no water. (col. 9, lines 3-15) Terada also teaches that known film formation processes including melt formation such as film formation by melt extrusion, blown film process, or injection molding; casting process can be employed for producing the films. (col. 6,. lines 20-25) Thus, there is no suggestion to combine the disclosure of Terada with the disclosure of Fuchs to arrive at the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Thus, all the claims are allowable over these references.

In view of the above discussion and amendment, it is respectfully submitted that the present application is in condition for allowance. Therefore, an early reconsideration and allowance are respectfully requested.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned would appreciate the opportunity to do so.

Respectfully submitted,

Date: December 18, 2002

By: _____

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 12 has been deleted.

The claims have been amended as follows:

1. (Twice Amended) A soluble film preparation for oral administration comprising a drug, an edible polymer and a monosaccharide or ~~a~~ an oligosaccharide, wherein the film is obtained by spreading and drying and has an elution rate of more than about 50% per 10 minutes and the drug is a compound enhanced in internal absorption by forming a solid solution with the edible polymer.

4. (Twice Amended) The soluble film preparation according to claim 1~~3~~, in which the compound is at least one of nilvadipine~~.~~, nifedipine, phenytoin, chloramphenicol, griseofulvin, or sulfamethizole.

8. (Twice Amended) The soluble film preparation according to claim 1, in which the oligosaccharide is reducing maltose starch syrup .

11. (Twice Amended) The soluble film preparation according to claim 1~~0~~, in which the compound is nilvadipine, the additional edible polymer is hydroxypropyl cellulose, and the starch syrup is reducing maltose starch syrup.